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REMARKS

In the Final Official Action dated July 31, 2006, claims 19-20 are pending and under examination. Claims 19 and 20 remain rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-21 of U.S. Patent No. 6,083,512 in view of Farmers and Consumers Market Bulletin (Department of Agriculture, Atlanta, Georgia, 70(24): 1984, page 1, 12, ill.) and Kensil (U.S. Patent No. 5,057,540). Claim 20 remains rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Seifert (*Deutsche Tiernarzliche Wochem.* 90(7): 274-279, 1983) in view of Geresi et al. (*Ann. Immunol. Hung.* 25: 37-40, 1985), Farmers and Consumers Market Bulletin, and Kensil. Claim 19 remains rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Seifert, Geresi et al., Farmers and Consumers Market Bulletin, and Kensil as applied to claim 20 above, and further in view of Green et al. (*The Veterinary Record* 120: 435-439, 1987).

In response to the double patenting rejection, Applicants will provide a terminal disclaimer in respect to U.S. Patent No. 6,083,512.

Regarding the obviousness rejections based on Seifert in combination with other references, Applicants previously submitted that the references, taken singularly or in combination, do not teach or suggest teach that the use of saponin alone as the adjuvant would be effective for clostridial antigens. However, the Examiner argues that the claim language is open. Specifically, the Examiner states that the adjuvant is characterized as "consisting essentially of a saponin". The Examiner has read the term "consisting essentially of" as open language, as the Examiner alleges that there is no clear indication in the specification or the claims as to the basic and novel characteristics of the claimed invention. In addition, the Examiner states that the

vaccine composition is characterized as "comprising" an adjuvant, i.e., the vaccine composition is not limited to saponin as the single adjuvant.

Applicants have amended independent claim 20 to recite that the vaccine composition comprising a saponin, wherein the saponin is the "sole adjuvant" in the vaccine composition. Applicants respectfully submit that the amendment is clearly supported by the specification. The present application demonstrates for the first time that a vaccine containing *Clostridium* antigens and saponin as the only adjuvant conferred effective protection to vaccinated animals. See, e.g., the results of potency tests described at page 11 and 15, and Tables 2 and 7 of the specification. No new matter is introduced by the instant amendment.

Applicants reassert that the primary reference to Seifert does not teach or remotely suggest that when a saponin is the sole adjuvant component in a multicomponent clostridial vaccine, the vaccine would have any protective efficacy.

As described in the present application, there was no recognition in the art that a water-soluble adjuvant such as saponin could be used as a sole adjuvant to enhance the immunogenicity of a multicomponent clostridial vaccine. Prior to the present invention, it was generally recognized that clostridial toxoids were soluble proteins of relatively low antigenicity and poor stability; and thus, clostridial vaccines required adjuvants, typically, aluminum compounds, in order to increase antigenic potency and to enhance stability. The present application demonstrates for the first time that a vaccine containing immunogens from two or more *Clostridium* species or serotypes conferred effective protection to vaccinated animals. See, e.g., the results of potency tests described at page 11 and 15, and Tables 2 and 7 of the specification.

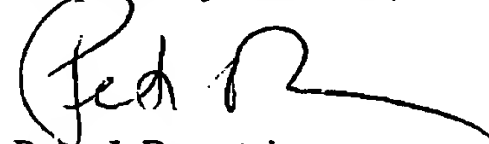
Applicants further respectfully submit that the deficiencies of the Seifert reference are not cured by any of the secondary references. In this regard, the Examiner, in referring to Figures 12 and 15 in Kensil, states that the use of saponins alone as an adjuvant was specifically demonstrated to be effective in providing an immune response against an antigen of interest.

Applicants respectfully draw the Examiner's attention to the fact that the antigen employed by Kensil in the experiments delineated in Figures 12 and 15 is bovine serum albumin (BSA). Applicants respectfully submit that BSA does not have the problems of low antigenicity and poor stability, which are associated with clostridial antigens. Therefore, those skilled in the art would not have readily extrapolated the results of Kensil to clostridial antigens. In other words, Applicants respectfully submit that those skilled in the art would not have gained a reasonable expectation of success in arriving at *the claimed invention* based on Kensil.

Therefore, Applicants respectfully submit that the cited references, either alone or in combination, do not teach or suggest a multicomponent clostridial vaccine composition formulated with saponin as the sole adjuvant, as presently claimed. As such, the rejections of both claims 19 and 20 based on the combination of the identified references are improper, and withdrawal thereof is respectfully requested.

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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